





**ETYMOTIC RESEARCH, INC.**

513(f) Reclassification Petition – TV-TIP Sound Amplifier

## **SECTION B – PETITION STATEMENT**

### **1. Introduction**

This petition follows the procedures for “new devices” under section 513(f) of the Act, and reclassification of certain devices. The content and form of the following petition is in accordance with Sec. 860.123.

### **2. Specification of Type of Device**

The type of device for which reclassification is requested:

Sound Amplifier

### **3. Statement of Action**

It is requested that the TV-TIP Sound Amplifier device be reclassified from class III, as classified by operation of section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) under the criteria in Sec. 860.3(c), to class I and exempt from premarket review under section 510(k) of the Act.